

Attorney Docket No.: UT-0048  
Inventors: Rao et al.  
Serial No.: 10/502,224  
Filing Date: May 17, 2005  
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#### **REMARKS**

Claims 1-10 are pending in the instant application. Claims 5-10 have been withdrawn from consideration by the Examiner. Claims 1-4 have been rejected. Reconsideration is respectfully requested in light of the following remarks.

#### **I. Finality of Restriction Requirement**

The Examiner has made final the Restriction Requirement mailed January 10, 2007. Claims 5-10 have been withdrawn from consideration by the Examiner as being drawn to a nonelected invention. However, the Examiner has acknowledged that upon allowance of the instant claimed precursor cells, they will be subject to rejoinder to claims 5-10. Accordingly, Applicants reserve the right to rejoin claims 5-10 upon allowance of the claimed precursor cells.

#### **II. Rejection of Claims 1-4 under 35 U.S.C. 112, first paragraph - Lack of Enablement**

Claims 1-4 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. The Examiner suggests that the instant specification does not provide an enabling disclosure for a pure homogenous population of mammalian astrocyte restricted

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precursor cells, being CD44 immunoreactive and generating astrocytes but not oligodendrocytes, or a method for isolating the same from embryonic or fetal tissues, ES cell culture or glial restricted precursor cells. The Examiner suggests that the specification states: "The astrocyte restricted precursor cells of the present invention do not express A2B5. Further these cells differ from stem and progenitor cell populations in their expression of CD44 and their ability to differentiate into astrocytes . . . but not oligodendrocytes". However, the Examiner suggests that the preceding is not in accord with the observations in the working examples.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that Examples 1 through 5 of the instant specification were included to describe culture conditions under which a multi-differentiating progenitor cell type (not the instant claimed astrocyte restricted precursor cells) differentiates into multiple cells types including astrocytes, oligodendrocytes and neuronal cells. As taught at page 8 of the instant specification, it is under conditions in which other populations differentiate into neurons or oligodendrocytes (such as exemplified in Examples 1-5) that

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the instant claimed population of cells does not express A2B5 and differs from stem and progenitor populations in its expression of CD44 and its ability to differentiate into astrocytes. These Examples were not provided as enablement for the instant claimed cells and the Examiner's focus on only the Examples section of the application to suggest that the instant specification lacks enablement is incorrect.

In accordance with MPEP 2164, the enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and use the invention. Teachings beginning at page 8, line 31 of the instant specification and ending at page 11, line 12 of the instant specification describe various methods for isolating the claimed astrocyte restricted precursor cells. Teachings beginning at page 11, line 13, of the instant specification and extending to page 15, line 13, describe various methods for using the claimed astrocyte restricted precursor cells. Further, Table 1 at page 7 of the instant specification sets forth multiple characteristics of the instant claimed cells. Thus, teachings in the specification at pages 7 through 15 clearly describe how to make and use the claimed invention, thus meeting the enablement requirements of 35 U.S.C. 112, first paragraph.

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Applicants disagree with the Examiner that prior art teachings such as Raff et al. and Carpenter relating to different cells types with different differentiation characteristics are in any way indicative of the instant claimed invention being unpredictable or requiring undue experimentation beyond teachings of the instant specification to develop methodologies for discovering an astrocyte restricted precursor cells. Applicants also respectfully disagree with the Examiner that the instant specification lacks sufficient guidance for the claimed invention, particularly given the detailed teachings of cell characteristics, methods for isolation of these cells and methods for use thereof at pages 7-15 of the instant specification.

In an earnest effort to advance the prosecution and to further address the Examiner's concerns regarding the CD44 positive cells of the instant invention being astrocyte restricted precursor cells, Applicants are submitting herewith a publication by Liu et al. (Developmental Biology 2004 276:31-46) which confirms that CD44 identifies an astrocyte restricted precursor cell that is committed to generating astrocytes (see Abstract of Liu et al.). These ARP cells were isolated in accordance with an exemplary

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method disclosed in the instant specification (see page 32-33 of Liu et al. and teachings in the specification at page 8-11). Detailed teachings of the culture conditions used to confirm that commitment of these cells to differentiation to astrocytes is disclosed at page 32 of Liu et al.

MPEP 2164.04 is clear; a specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirements of 35 U.S.C. 112, first paragraph, unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support. The instant specification, which teaches characteristics of the astrocyte restricted precursor cells as well as methods for their isolation and uses thereof, and whose teachings are confirmed by Liu et al. (Developmental Biology 2004 276:31-46), is clearly in compliance with this requirement.

Withdrawal of this rejection under 35 U.S.C. 112, first paragraph, is therefore respectfully requested.

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**III. Rejection of Claims 1-4 under 35 U.S.C. 102(e)**

Claims 1-4 have been rejected under 35 U.S.C. 102(e) as being anticipated by Carpenter (U.S. Patent 6,833,269).

Applicants respectfully traverse this rejection.

It is respectfully pointed out that the basis for this rejection is flawed as the Examiner relies upon Example 3 of the instant specification to suggest that the claim language of "astrocyte restricted" is non-limiting because the ability of cells to differentiate into astrocytes, but not oligodendrocytes is a consequence of culturing conditions. As discussed in Section II, supra, Examples 1 through 5 of the instant specification were included to describe culture conditions under which a multi-differentiating progenitor cell type (not the instant claimed astrocyte restricted precursor cells) differentiates into multiple cell types including astrocytes, oligodendrocytes and neuronal cells. As taught at page 8 of the instant specification, it is under conditions in which other populations differentiate into neurons or oligodendrocytes (such as exemplified in Examples 1-5) that the instant claimed population of cells does not express A2B5 and differs from stem and progenitor populations in its expression of CD44 and its ability to differentiate into astrocytes. Confirmation of teachings of

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the claimed CD44 immunoreactive cells generating astrocytes but not oligodendrocytes is provided by Liu et al. (Developmental Biology 276 (2004):31-46).

Accordingly, contrary to the Examiner's suggestion, "astrocyte restricted" is a limiting characteristic of the claimed invention which is not simply a consequence of culturing conditions.

Carpenter does not teach CD44 immunoreactive cells that are astrocyte restricted and fail to generate oligodendrocytes. In fact, the Examiner acknowledges at page 7 of the instant Office Action that the prior art (clearly inclusive of Carpenter since it is discussed at page 6 of the Office Action) is silent on mammalian neuroprogenitor cells that are astrocyte restricted and fail to generate oligodendrocytes.

Accordingly, Carpenter cannot anticipate the instant claimed invention.

Withdrawal of this rejection under 35 U.S.C. 102(e) is therefore respectfully requested.

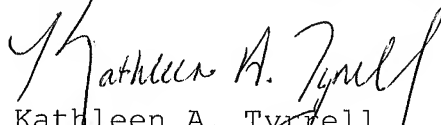
#### **IV. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

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Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
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Date: August 13, 2007

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